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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,093	06/18/2001	F.C. Thomas Allnutt	031676.0247	7694

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HUNTON & WILLIAMS  
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EXAMINER

DAVIS, DEBORAH A

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/882,093

Applicant(s)

ALLNUTT ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 15-19, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claims are related as product, method of making and method of use and that the search will be coextensive for all three groups. This is not found persuasive because all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 15 recites the limitation "a particular entity" in line 1, is vague and indefinite because it is unclear as to what that particular entity refers to.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schluchter et al (The Journal of Biological Chemistry, Vol. 272, No. 21, Issue May 23, pp. 13562-13569) in view of Stryer et al (USP#4,859,582).

Schluchter et al teaches the characterization of the enzyme cyanobacterial BvdR (biliverdin Reductase) that has an affinity for the substrates of several fusion proteins, such as phycocyanobilin, phytochromobilin and phycoerythrobilin, which are all phycobiliproteins that contain protein domains. One such phycobiliprotein is the phycocyanobilin fusion protein that comprise of a cyanobacterial (1<sup>st</sup> domain) and a biliverdin (2<sup>nd</sup> domain). When the enzyme cyanobacterial BvdR was reacted with the phycocyanobilin, a detectable product was produced with a visible wavelength of 429nm, which is a known biological affect (pg. 13567-13568, paragraphs 1 & 2).

Schluchter et al does not teach utilizing phycobiliproteins or detection methods in an assay configuration.

However, Stryer et al teaches an assay using a variety of phycobiliproteins in immunoassays or competitive protein binding assays where subject phycobiliproteins serve as fluorescent labels. The phycobiliproteins may be conjugated to a ligand, a receptor, or an antibody. The phycobiliproteins have many favorable properties such as

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high absorption coefficients in the longer wavelength visible spectral region, high fluorescence quantum yields; they are stable proteins and have good storage stability. Phycobiliproteins are also highly soluble in aqueous solutions and can readily be coupled to a wide range of biologically specific molecules; they do not bind **non-specifically** to cells and are 30 more times intense as that of fluorescein conjugates.

It would have been obvious to one of ordinary skill in art to use the various fusion proteins (phycobiliproteins) of Schluchter et al in the assay configuration of Stryer et al because they have good spectral characteristics, and longer wavelength emissions, good storage stability and they are highly soluble in aqueous solutions. With respect to claims 17-19, one of ordinary skill in the art would utilize known enzymes such as a ribozyme, phosphokinase or a protease in the enzymatic assay systems taught by Schluchler et al in view of Stryer et al to get the same results as the instant application. These modifications with respect to the particular enzyme employed are routine optimizations that are almost always varied and used in immunoassay studies. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been **prima facie** obvious for one of ordinary skill in the art to substitute the known enzymes of claims 17-19 in the given assay parameters to assess biological activity as a means of optimizing the assays provided by the art.

### ***Conclusion***

7. No claims are allowed.

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8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Collier et al (J. Mol. Biol., 1995) discloses the evolution of the phycobiliproteins.

B. Mao et al (WO99/15517) discloses dyes and dye-conjugates that are useful as fluorescent probes, particularly in biological samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

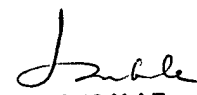
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123.



Deborah A. Davis  
CM1, 7D16  
February 24, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

02/24/03

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